(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 063 900 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication of patent specification: **30.12.86**

(51) Int. Cl.[4]: **A 61 B 5/00**, A 61 B 5/02

(21) Application number: **82301939.3**

(22) Date of filing: **15.04.82**

# (54) Method and device for measuring blood flow in blood vessels.

(30) Priority: **17.04.81 US 255247**
**07.12.81 US 327785**

(43) Date of publication of application:
**03.11.82 Bulletin 82/44**

(45) Publication of the grant of the patent:
**30.12.86 Bulletin 86/52**

(84) Designated Contracting States:
**AT BE CH DE FR GB IT LI LU NL SE**

(56) References cited:
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**US-A-3 589 360**
**US-A-3 623 473**
**US-A-4 191 194**

**REPORTS ON PROGRESS IN PHYSICS, vol.39, no.1, January 1976 J.P.WOODCOCK: " Physical properties of blood and their influence on blood-flow measurement" pages 92-98**

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EP 0 063 900 B1

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## Description

This invention relates to apparatus for monitoring of blood flow and more particularly to the monitoring of blood flow with an implantable device, especially suitable for use in conjunction with both micro- and macrosurgical procedures.

The principle of reconstructive vascular surgery is to provide and maintain blood flow to tissues and organs. With circulatory interruption distal tissues become ischemic. Over time this ischemia progresses from a reversible form (one in which restoration of blood flow re-establishes tissue viability) to an irreversible form (one in which there is cell death and irrevocable tissue damage).

Of prime importance is the monitoring of patients, and specifically those areas which have been vascularized, so that if there is circulatory embarrassment it is discovered during the period of reversible ischemia. With early intervention and correction, tissue viability is restored and preserved.

Various techniques have been employed in the past for measuring blood flow in large and small blood vessels. These have included direct observation (blanche and refill technique) in tissues with a cutaneous component; the use of Doppler and ultra sound monitors, as well as transcutaneous oxygen probes and laser optic monitors. Tracer scans, arteriography, and electro-magnetic flow meters have all been used. All of these approaches are limited in that they are either episodic in their monitoring, risky in their application, or not entirely reliable in their interpretation.

Blood flow measurements have also been undertaken using a thermostromuhr. A thermostromuhr in essence comprises a plastic block or support containing two heating electrodes and electrical temperature sensing means comprising two thermocouples. After implanting the block surgically, the blood vessel is inserted into a cylindrical passage through the block *via* a slit in said block, so that the walls of the blood vessel are in close contact with the passage; the electrodes and thermocouples are disposed in the passage for contact with the blood vessels.

The thermostromuhr, its operation and problems are discussed in Reports on Progress in Physics, Vol. 39, No. 1, January 1976 pages 92—98.

FR—A 2,393,283 discloses a temperature-measuring probe in the form of a needle containing a thermocouple element in a central passage thereof, the thermocouple junction being located as close as possible to the tip of the needle. Such a probe construction would not be suitable for placement in intimate association with the wall of a blood vessel for the purpose of monitoring blood flow.

Similarly, US—A—3,589,360 discloses a thermistor flowmeter device which includes a probe containing a thermistor. In use, the probe is inserted through the wall of an artery, which is thus punctured by the probe.

IBM Technical Disclosure Bulletin, Vol. 17, No. 1, June 1974 discloses an implantable temperature probe comprising a thermistor sealed inside a length of vinyl tubing, which when pulled, enables the probe to be extracted from the body.

What is needed is a monitor that can be placed under direct vision next to a vessel and which would give continuous, reliable information regarding blood flow through that vessel, and which would warn of any flow abnormalities; when no longer needed the monitor should have the ability to be removed atraumatically and transcutaneously, i.e. without resorting to a surgical technique, which is an impossibility with the thermostromuhr. Its use should be valid in all types of vascular surgery (microsurgical and macrosurgical) and in all types of repairs (arteries, veins, vein grafts and prosthetic grafts). Uses may also include monitoring organ function, for example for diagnosis.

In one manner of using the present invention, blood flow within vessels is determined by measuring the temperatures of the blood vessels, both proximal and distal to an anastomatic repair. This may be done by measuring these temperatures that exist ambiently within the body on a continual basis or by providing heat to the system and noting the rates of dissipation proximal and distal to the anastomatic repair. A device according to the invention includes a thermal sensor which can be placed over a portion of the blood vessel with leads taken out transcutaneously to a temperature monitor, the device — unlike a thermostromuhr — being constructed to be easily removable from the body without use of a surgical technique.

By means of the invention, therefore, the monitoring of blood flow in a blood vessel involves the steps of (a) placing a thermal sensor next to the wall of the blood vessel, (b) monitoring temperature sensed by the sensor, and (c) providing an output indication of change in the sensed temperature as indicative of a change in blood flow within the vessel.

According to the invention, there is provided a device for monitoring blood flow within blood vessels in a human or animal body which utilises a surgically implantable temperature sensor and comprises an electrical temperature sensing element, electrical leads connected thereto and a tube within which the sensing element and the leads are housed, characterised in that the tube, for disposing the sensing element adjacent a blood vessel for heat transfer therewith and for supporting the sensing element, has an end portion cut away to form a trough-shaped section to conform in part to the shape of the blood vessel, the sensing element being fixed to the inner surface of the trough-shaped section which, being a stream-lined continuation of the tube, in use permits atraumatic and transcutaneous removal of the surgically implanted sensor from the temperature measuring site by the application of tension to the tube along the direction in which the leads extend from the sensing element.

The device according to this invention is im-

plantable adjacently about a blood vessel. Detection of a low temperature is indicative of an occlusion upstream of the device. Use of two such devices, one upstream and one downstream of a potential occlusion will reveal such a occlusion when a temperature difference is detected. In some cases, where implantation is deep within a body, occlusion-indicative temperature perturbations may be masked. In such an event, current may be passed through the sensor(s) and monitored for loss of heat indicative of an adjacent occlusion.

Embodiments of the invention will be described hereinafter by way of non-limitative example with reference to the accompanying drawings, in which:

Fig. 1 is an illustration in perspective view of a blood flow monitor constructed in accordance with this invention;

Fig. 2 is a cross-sectional view of the monitor of Fig. 1;

Fig. 3 is an illustration of monitors constructed in accordance with this invention attached at proximal and distal locations on a blood vessel for monitoring blood flow therein;

Fig. 4 is an illustration in perspective view of another embodiment of a monitor constructed in accordance with this invention; and

Figs. 5a, b, c and d are illustrations in schematic form of an example of the practice of the method of monitoring blood flow.

Referring to Figs. 1 and 2, there is illustrated one embodiment of the device of the invention. A silicon elastomer tubing 10, which typically would be formed of a tubing having 1.1 mm internal diameter and 1.7 mm external diameter, has one end cut away leaving a semilunar cap section or trough 14, in which is embedded a thermal sensor in the form of a thermocouple 16. Electrical leads 15 from the thermocouple 16 are brought out through the full tubing section 12 of the elastomer tube. The semi-lunar cap, or sheath, is placed in close juxtaposition around blood vessel 6, with the thermocouple element 16 immediately adjacent to the adventitia of the vessel. The thermocouple 16 may be any suitable thermocouple such as those manufactured as type T by Omega Electronics, Hartford, Connecticut. A suitable thermocouple was made by stripping Teflon ® insulation from the ends of matched, 3 mil constantan and chromel alloys. After twisting the ends together on one side and soldering them, the thermocouple junction was insulated by dipping in a dilute solution of lacquer and glyptol. While a thermokcouple is illustrated in Fig. 1, the temperature sensor could be formed of a thermistor or any other suitably sized, suitably sensitive, temperature detector.

The polymer housed thermocouple unit which FIGURES 1 and 2 illustrate is specifically designed such that the thermocouple and its insulation are enclosed within the polymer cylinder. The polymer cylinder is flattened and semilunar at one end and is structured in such a way to allow the thermocouple junction to remain only a fraction of a millimeter from the surface temperature to be measured. The polymer housing is constructed in such a way as to allow laxity of thermocouple wiring within the polymer housing such that any longitudinal traction on the housing will not disrupt and damage the thermocouple. Further, the polymer housing of a silicone or other typical inert flexible, stretchable and malleable material is made in such a way as to allow a suture needle to be driven easily through the housing with which attachment of the housing to an appropriate tissue location can be utilized. The various sizes of the polymer housing are made to appropriately fit the tissue mounting purpose which is required in the specific clinical use. Further, the housing is constructed in such a way with a smooth external surface such that adherence to surrounding tissues is minimized and, thus, the entire unit can be extracted transcutaneously from the indwelling wound in a trauma-free way.

With reference to Fig. 3, the blood flow monitor of the invention is shown implanted within the human leg. In this embodiment, a control sensor 20 is sutured to the perivascular tissue around artery 30 at a location above the point of anastomisis to the artery of the vascularized tissue transfer (flap) 34. A second probe 22, identical to the first, is sutured, again through sutures 24 to the perivascular tissue around the artery 30 at a point proximal to the vascularized tissue flap 34. The leads 25 and 27, respectively, from the control probe and the flap probe, are brought out through the skin to connect to a temperature monitor 30. The monitor as is illustrated schematically can present separate readings for temperature of the control probe and the flap probe, or could be arranged to provide only a differential temperature output. Additionally, the monitor 30 is shown as providing an alarm, which will provide a visual or audio output when the differential between the temperature at the control probe and the flap probe exceeds a predetermined amount. A suitable monitor is that sold under the type designation TH—6, by Bailey Instrument Inc. of Saddle Brook, New Jersey.

Procedurally, the probes illustrated in Figs. 1, 2 and 3 are attached with sutures to the tissue around the artery after completion of the surgical anastomisis, and the leads are taken out through the skin in a manner similar to drains. The wound is then closed and the temperature monitored on a continual basis. It has been found, in animal tests, that occlusion of the artery will result in a temperature drop of approximately 1° Centigrade. This is in contrast to a significantly lesser drop in temperature as measured by the two probes when the artery is patent. When the monitor is no longer needed, approximately 72 hours after completion of the surgery, the sutures 24 have absorbed and the leads may be atraumatically and transoutaneously removed.

In Fig. 4 there is illustrated a second embodiment of a sensor configuration suitable for use in the invention. In the probe of Fig. 4, the silicone

elastomer tubing 40 has had a section at the end cut as shown to produce a series of tabs 42. A heat sensor 46, which would typically be a thermistor or thermocouple, is again embedded in the upper wall of the sheath in a manner similar to that described for the embodiment of Fig. 2. In application, the probe of Fig. 4 is slipped over the artery and is held in place by virtue of the gripping action of the tabs 42. In this embodiment, then, no sutures would be utilized.

A monitor or probe for practice of the invention thus has a support element that carries a thermal sensor element. The support element is of readily sterilized, surgical grade, electrically insulating material which is chemically inert to the body in which it is implanted. Further, to facilitate removal of the probe, the material is of a character to which body tissue does not adhere or cling and into which tissue does not grow. The support element is configurated to dispose the thermal element in the desired heat transfer relation with the tissue being monitored. The illustrated support element structures have at least a partial tubular configuration to dispose the thermal element close to, if not contiguous with, a vascular body member, e.g. a vessel. In one illustrated instance, i.e. FIGURE 1, the support element is sutured in place, and in another instance, i.e. FIGURE 4, the support element is configured for resiliently and releasably attaching to the vascular member.

The support element preferably is arranged, moreover, for atraumatic and transcutaneous removal from the implantation site being monitored simply upon pulling on the electrical leads from the thermal element. This feature of a support element calls for the probe to be elongated longitudinal with the extension of the leads from the sensor element and to have sufficient pliability and streamlined configuration (e.g. be free of rigid lateral protruberances) for safe extraction in this manner from the body in which it is implanted.

As further described, the thermal sensor element is affixed to the support element, typically on or recessed in an inner tubular surface thereof.

In Fig. 5 there is illustrated a series of experiments demonstrating the use of this invention, utilizing the principles of heat generation through frictional flow. Thermistor monitors were used to correlate temperature drops with occlusions in one-to-two mm blood vessels in experimental animals. In Sprague-Dawley rats, New Zealand white rabbits, and mongrel dogs, three flow-occlusion models were tested with implantable thermistor monitors to directly measure vessel temperature. In Fig. 5a there is illustrated a single sensor monitoring of a femoral artery with repeated occlusions and releases. This experiment was carried out with six 300 mg Sprague-Dawley rats. In Fig. 5b, there is illustrated schematically the simultaneous monitoring of a femoral artery with monitors proximal and distal to a situs of occlusion. This experiment was carried out with three 300 mg Sprague-Dawley rats, two 3 kg New Zealand white rabbits and two 30 kg mongrel dogs. In Fig. 5c there is illustrated the simultaneous monitoring of the arterial inflow into an isolated epigastric flap, based on the inferior epigastric vessels, with and without occlusion. This experiment was carried out on five 3 kg New Zealand white rabbits.

In all the experiments illustrated schematically in Fig. 5 the blood vessels were exposed and the sensors secured with the thermistors flush to the adventitia of the particular vessels. The signal lines from the sensors were brought out through separate sites. A standard vessel occlusion loop was placed around the femoral artery and also brought out with a small catheter through a separate opening. The wounds were then closed. Free flowing base line data was established and thereafter the vessels were occluded. After data related to the occlusion was recorded, the occlusion loop was reopened and flow data again recorded. At the conclusion of each of the experiments the sensors were removed transcutaneously and the wound was then opened and the vessels examined for injury.

The results of the above described experiments were as follows:

a) the occlusion of the vessels in the rats resulted in a 1° Centigrade drop in temperature at the point distal to the point of occlusion,

b) occluding the blood vessels in rabbits and dogs resulted in a 0.5° Centigrade drop in temperature at a point distal to the point of occlusion,

c) in all of the experiments reestablishment of the flow following the removal of the occlusion resulted in all of the temperature readings returning to the previous base line,

d) the transcutaneous removal of the sensor resulted in no trauma to the blood vessels.

In the preferred method described the blood flow through the vessels results in maintenance of temperature at the sensors, while occlusion results in decreased temperature. However, there may be situations, for example in locations deep within a body, where the ambient temperature is sufficiently high so that even when the vessel is occluded the temperature will not drop appreciably. One method which may be used under such circumstances is to provide heat to the sensors, for example electrical current to the thermocouples. Blood flow through the vessel will then cool the thermocouples at an essentially equal rate. If, however, there is an occlusion, the lack of flow within the vessel at the sensor distal to the occlusion will result in a slower rate of cooling at that sensor. This differential may be monitored by conventional techniques, thus providing an indication of occlusion.

It is believed that the utility of the monitor of this invention in diagnosing vascular disturbance within a free tissue transfer can include topical application of the probe on the surface of the free tissue transfer or within the substance of the transfer itself. Although the temperature differen-

tial between a proximal vessel and a distal vessel supplying the transfer, as exemplified in the foregoing illustrated embodiments, may be amongst the most sensitive methods of tissue transfer monitoring, it is considered that other sources of heat production may be used as the control source within the body, such as an adjacent viscus or muscle which is deep within the body or extremity, and utilize the parenchyma of the transferred tissue as the monitoring surface analogous to the distal artery. This technique may be particularly useful where the medical risk of placing the probe in contact with the vessel is extensive and there is acceptable reliability in placing the thermocouple in contact with the tissue to be transferred or a proximal heat source.

**Claims**

1. A device for monitoring blood flow within blood vessels in a human or animal body which utilises a surgically implantable temperature sensor and comprises an electrical temperature sensing element (16), electrical leads (15) connected thereto and a tube (10) within which the sensing element and the leads are housed, characterised in that the tube (10), for disposing the sensing element adjacent a blood vessel for heat transfer therewith and for supporting the sensing element has an end portion cut away to form a trough-shaped section (14) to conform in part to the shape of the blood vessel, the sensing element (16) being fixed to the inner surface of the trough-shaped section (14) which, being a streamlined continuation of the tube, (10) in use permits atraumatic and transcutaneous removal of the surgically implanted sensor from the temperature measuring site by the application of tension to the tube (10) along the direction in which the leads (15) extend from the sensing element (16).

2. A device in accordance with claim 1, further characterised by monitor indicating means (30) connected with the sensing element (16) for receiving an electrical signal therefrom to provide an output indicative of changes in temperature sensed by the sensing element (16).

3. A device in accordance with claim 2, further characterised by a second tube having a second temperature sensing element fixed to it, the said monitor being operative to provide an output indicative of the differential in temperatures sensed by the two sensing elements.

4. A device in accordance with any of claims 1 to 3, wherein the tube (10) is a biologically inert material, for example made from a silicone elastomer, and the sensing element (16) is a thermocouple or thermistor.

**Patentansprüche**

1. Vorrichtung zum Überwachen des Blutstroms innerhalb von Blutgefäßen in einem menschlichen oder Tierkörper, die einen operativ einsetzbaren Temperatur-sensor verwendet und einem elektrischen Temperaturfühler (16), mit diesem verbundene elektrische Leitungen (15) und ein Rohr (10) umfaßt, in dem der Fühler und die Leitungen untergebracht sind, dadurch gekennzeichnet, daß das Rohr (10) für eine an ein Blutgefäß zur Wärmeübertragung angrenzende Anbringung des Fühlers und zu dessen Abstrützung einen abgeschnittenen Endbereich zur Bildung eines trogförmigen Abschnitts (14) aufweist, um teilweise der Form des Blutgefäßes zu entsprechen, und der Fühler (16) an der Innenfläche des trogförmigen Abschnitts (14) festgelegt ist, der, als stromlinienförmige Fortsetzung des Rohres (10), im Anwendungsfall eine atraumatische und transkutane Entfernung des operativ eingesetzten Sensors von der Temperaturmeßstelle durch die Anwendung von Spannung am Rohr (10) in der Richtung ermöglicht, in die sich die Leitungen (15) vom Fühler (16) aus erstrecken.

2. Vorrichtung nach Anspruch 1, gekennzeichnet durch eine Monitor-Anzeigeeinrichtung (30), die mit dem Fühler (16) zum Empfang eines elektrischen Signals von diesem zur Abgabe eines Ausgangs als Anzeige von durch den Fühler (16) gemessenen Temperaturänderungen verbunden ist.

3. Vorrichtung nach Anspruch 2, gekennzeichnet durch ein zweites Rohr mit einem zweiten an diesem festgelegten Temperaturfühler, wobei der Monitor in der Weise arbeitet, daß ein den Unterschied in den von den beiden Fühlern gemessenen Temperaturen anzeigender Ausgang abgegeben wird.

4. Vorrichtung nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß das Rohr (10) aus einem biologisch inerten Material besteht, beispielsweise von einem Silikon-Elastomer gebildet ist, und der Fühler (16) ein Thermoelement oder Thermistor ist.

**Revendications**

1. Dispositif de surveillance du flux sanguin dans les vaisseaux sanguins d'un animal ou d'un être humain, utilisant un capteur de température implantable par chirurgie et comprenant un élément thermosensible électrique (16), des conducteurs électriques (15) connectés à cet élément et un tube (10) dans lequel sont logés l'élément thermosensible et les conducteurs, caractérisé en ce que pour pouvoir placer l'élément thermosensible dans une position adjacente à un vaisseau sanguin, afin d'assurer un échange de chaleur avec celui-ci, et pour supporter l'élément thermosensible le tube (10), comporte une partie extrême découpée de manière à former une section (14) ayant la forme d'une auge, afin de s'adapter en partie à la forme du vaisseau sanguin, l'élément thermosensible (16) étant fixé à la surface interne de la section (14) en forme d'auge qui, du fait qu'elle se trouve formée dans le prolongement continu du tube (10) utilisé, permet un enlèvement sans traumatisme et transcutané du capteur implanté chirurgicalement, à partir de l'endroit où s'effectue la mesure de la tempéra-

ture, et ce par l'application d'une traction au tube (10) dans la direction suivant laquelle les conducteurs (15) s'étendent à partir de l'élément thermosensible (16).

2. Dispositif suivant la revendication 1 caractérisé en ce qu'il comporte en outre un indicateur de surveillance (30) connecté à l'élément thermosensible (16) pour recevoir de celui-ci un signal électrique et fournir un signal de sortie représentant des variations de la température relevée par l'élément thermosensible (16).

3. Dispositif suivant la revendication 2 caractérisé en ce qu'il comprend en outre un second tube sur lequel est fixé en second élément thermosensible, l'indicateur de surveillance intervenant pour fournir un signal de sortie représentant la différence des températures relevées par les deux éléments thermosensibles.

4. Dispositif suivant l'une quelconque des revendications 1 à 3 caractérisé en ce que le tube (10) est constitué en un matériau inerte biologiquement, tel que par exemple un élastomère silicone, et l'élément thermosensible (16) est un thermocouple ou une thermistance.

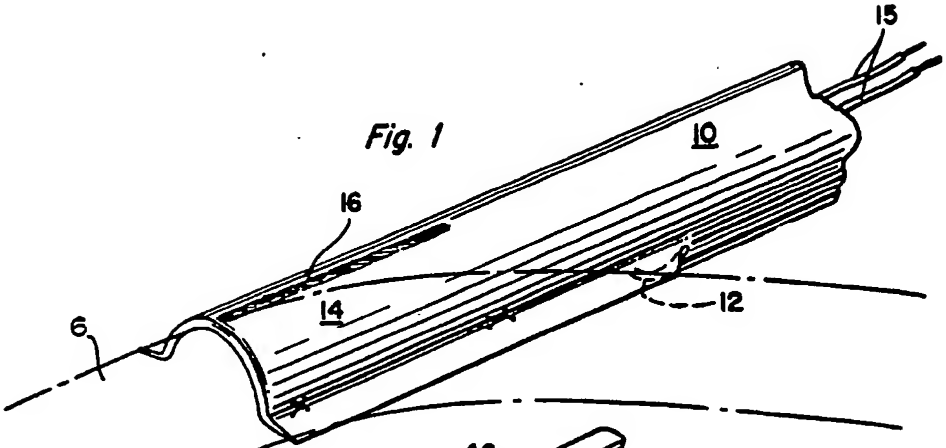



Fig. 1

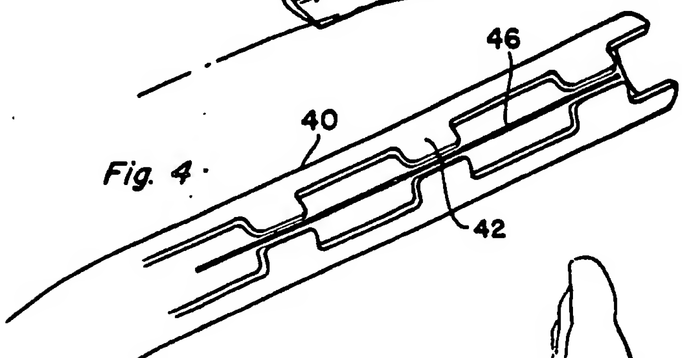



Fig. 4

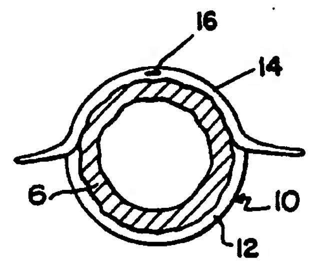



Fig. 2

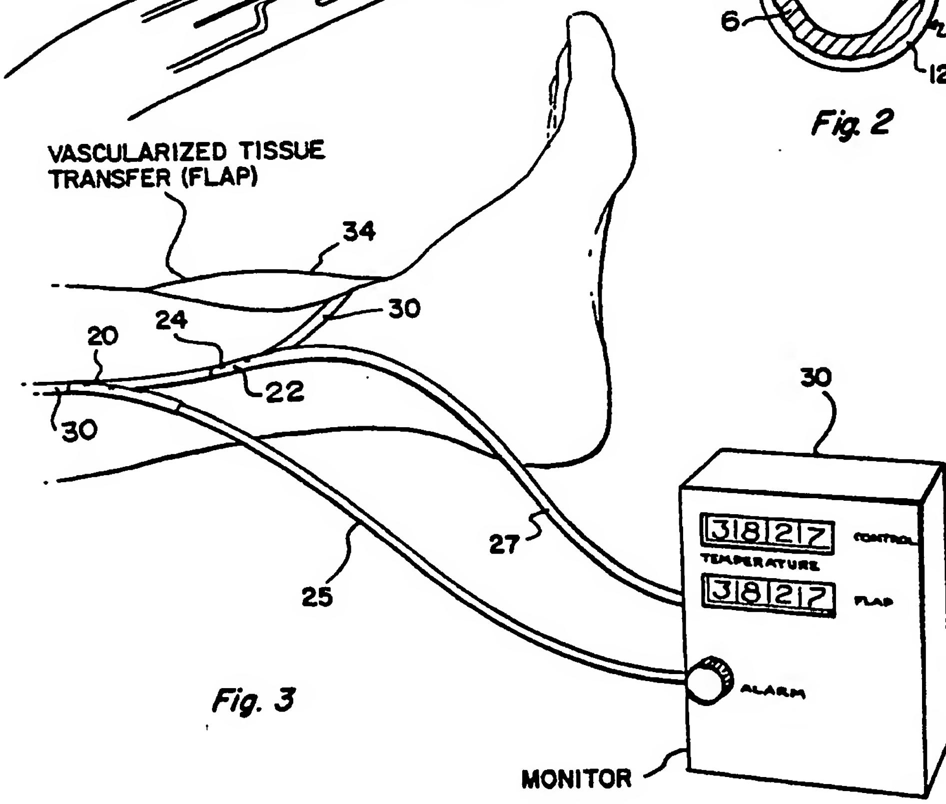



Fig. 3

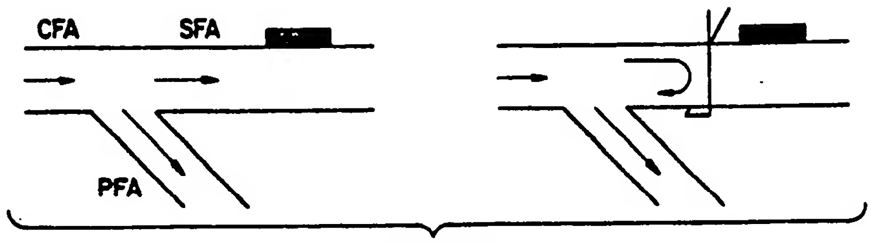



Fig. 5a

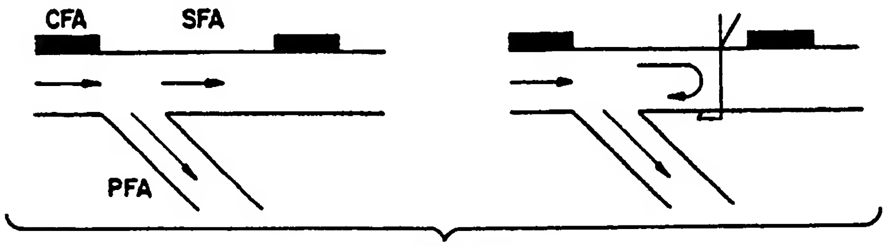
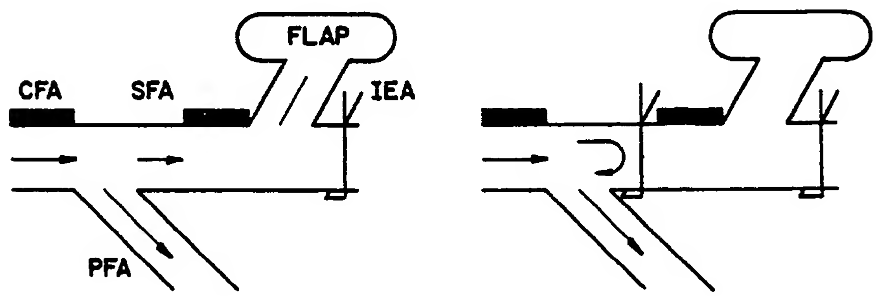



Fig. 5b




CFA – COMMON FEMORAL ARTERY

SFA – SUPERFICIAL FEMORAL ARTERY

PFA – PROFUNA FEMORIS ARTERY

IEA – INFERIOR EPIGASTRIC ARTERY

MONITOR

Fig. 5c